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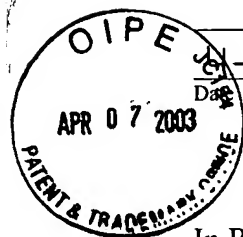
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April 4, 2003  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Jenny LOUIE-HELM et al.

Confirmation No.: 1055

Serial No.: 10/014,750

Group Art Unit: 1615

Filing Date: October 25, 2001

Examiner: Blessing M. Fubara

Title: FORMULATION OF AN ERODIBLE, GASTRIC RETENTIVE ORAL DOSAGE FORM USING IN VITRO DISINTEGRATION TEST DATA

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, DC 20231

Sir:

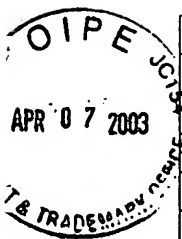
This is a Supplemental Information Disclosure Statement submitted for the Examiner's consideration. Applicants respectfully request that the Examiner review and make of record the references identified below.

PTO-1449 forms listing the references accompany this paper. Applicants would appreciate the Examiner's initialing and returning the forms to indicate that the references have been reviewed and made of record. The references are as follows:

U.S. PATENT DOCUMENTS		
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant
4,434,153	2/28/84	Urquhart et al.
4,690,824	9/1/87	Powell et al.
4,748,023	5/31/88	Tamás et al.
4,786,503	11/22/88	Edgren et al.
4,839,177	6/13/89	Colombo et al.
4,851,232	7/25/89	Urquhart et al.
4,865,849	9/12/89	Conte et al.
5,064,656	11/12/91	Gergely et al.
5,085,865	2/4/92	Nayak
5,213,808	5/25/93	Bar-Shalom et al.
5,232,704	8/3/93	Franz et al.
5,393,765	2/28/95	Infeld et al.
5,422,123	6/6/95	Conte et al.
5,458,887	10/17/95	Chen et al.

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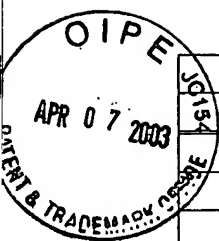
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U.S. PATENT DOCUMENTS		
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant
5,458,888	10/17/95	Chen
5,464,633	11/7/95	Conte et al.
5,472,708	12/5/95	Chen
5,487,901	1/30/96	Conte et al.
5,508,040	4/16/96	Chen
5,549,913	8/27/96	Colombo et al.
5,609,590	3/11/97	Herbig et al.
5,626,874	5/6/97	Conte et al.
5,650,169	7/22/97	Conte et al.
5,651,985	7/29/97	Penners et al.
5,681,583	10/28/97	Conte et al.
5,688,776	11/18/97	Bauer et al.
5,736,159	4/7/98	Chen et al.
5,780,057	7/14/98	Conte et al.
5,811,126	9/22/98	Krishnamurthy
5,837,379	11/17/98	Chen et al.
5,840,329	11/24/98	Bai
5,897,874	4/27/99	Stevens et al.
5,916,595	6/29/99	Chen et al.
6,033,685	3/7/00	Qiu et al.
6,207,197	3/27/01	Illum et al.
6,261,601	7/17/01	Talwar et al.
6,340,475	01/22/02	Shell et al.
6,368,628	4/9/02	Seth
6,451,808	9/17/02	Cowles
6,488,962	12/3/02	Berner et al.
2001/0018070	8/30/01	Shell et al.
Serial No. 09/425,491	Filed 10/22/99	Shell et al.
Serial No. 10/029,134	Filed 10/25/01	Gusler et al.
Serial No. 10/045,823	Filed 11/6/01	Shell et al.
Serial No. 10/066,146	Filed 2/1/02	Lim et al.
Serial No. 10/152,914	Filed 5/20/02	Fara et al.
Serial No. 10/280,309	Filed 10/25/02	Berner et al.
Serial No. 10/280,852	Filed 10/25/02	Devane et al.

FOREIGN PATENT DOCUMENTS		
Document No.	Publication Date	Country
EP 0598309 B1	1/28/98	Europe
EP 0795324 A2	9/17/97	Europe
GB 1330829	9/19/73	United Kingdom
WO 96/32097 A1	10/17/96	PCT
WO 98/55107 A1	12/10/98	PCT
WO 00/23045 A1	4/27/00	PCT

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### FOREIGN PATENT DOCUMENTS

Document No.	Publication Date	Country
WO 00/38650 A1	7/6/00	PCT
WO 01/32217 A3	5/10/01	PCT
WO 01/56544 A3	8/9/01	PCT
WO 01/97783 A1	12/27/01	PCT
WO 02/083687 A1	10/24/02	PCT

### NONPATENT DOCUMENTS

Abrahamsson, et al. (1993), "Absorption, Gastrointestinal Transit, and Tablet Erosion of Felodipine Extended-Release (ER) Tablets," <i>Pharmaceutical Research</i> 10(5):709-714.
Apicella et al. (1993), "Poly(ethylene oxide) (PEO) and Different Molecular Weight PEO Blends Monolithic Devices for Drug Release," <i>Biomaterials</i> 14(2):83-90.
Baumgartner et al. (2000), "Optimisation of Floating Matrix Tablets and Evaluation of Their Gastric Residence Time," <i>International Journal of Pharmaceutics</i> 195:125-135.
Bettini et al. (1994), "Swelling and Drug Release in Hydrogel Matrices: Polymer Viscosity and Matrix Porosity Effects," <i>European Journal of Pharmaceutical Sciences</i> 2:213-219.
Chen et al. (2000), "Gastric Retention Properties of Superporous Hydrogel Composites," <i>Journal of Controlled Release</i> 64:39-51.
Columbo et al. (1990), "Drug Release Modulation by Physical Restrictions of Matrix Swelling," <i>International Journal of Pharmaceutics</i> 63:43-48.
Davis et al. (1986), "The Effect of Density on the Gastric Emptying of Single- and Multiple-Unit Dosage Forms," <i>Pharmaceutical Research</i> 3(4):208-213.
Deshpande et al. (1997), "Development of a Novel Controlled-Release System for Gastric Retention," <i>Pharmaceutical Research</i> 14(6):815-819.
Ford et al. (1987), "Importance of Drug Type, Tablet Shape and Added Diluents on Drug Release Kinetics from Hydroxypropylmethylcellulose Matrix Tablets," <i>International Journal of Pharmaceutics</i> 40:223-234.
Gao et al. (1996), "Swelling of Hydroxypropyl Methylcellulose Matrix Tablets. 2. Mechanistic Study of the Influence of Formulation Variables on Matrix Performance and Drug Release," <i>Journal of Pharmaceutical Sciences</i> 85(7):732-740.
Hwang et al. (1998), "Gastric Retentive Drug-Delivery Systems," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 15(3):243-284.
Ju et al. (1995), "Drug Release from Hydrophilic Matrices. 1. New Scaling Laws for Predicting Polymer and Drug Release Based on the Polymer Disentanglement Concentration and the Diffusion Layer," <i>Journal of Pharmaceutical Sciences</i> 84(12):1455-1463.
Ju et al. (1995), "Drug Release from Hydrophilic Matrices. 2. A Mathematical Model Based on the Polymer Disentanglement Concentration and the Diffusion Layer," <i>Journal of Pharmaceutical Sciences</i> 84(12):1464-1477.
Kaniwa et al. (1983), "The Bioavailability of Flufenamic Acid and Its Dissolution Rate from Capsules," <i>International Journal of Clinical Pharmacology, Therapy and Toxicology</i> 21(2):56-63.
Kim (1995), "Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets," <i>Journal of Pharmaceutical Sciences</i> 84(3):303-306.
Lapidus et al. (1966), "Some Factors Affecting the Release of a Water-Soluble Drug from a Compressed Hydrophilic Matrix," <i>Journal of Pharmaceutical Sciences</i> 55(8):840-843.

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NONPATENT DOCUMENTS

Lapidus et al. (1968), "Drug Release from Compressed Hydrophilic Matrices," <i>Journal of Pharmaceutical Sciences</i> <u>57</u> (8):1292-1301.
Maggi et al. (2000), "High Molecular Weight Polyethylene Oxides (PEOs) as an Alternative to HPMC in Controlled Release Dosage Forms," <i>International Journal of Pharmaceutics</i> <u>195</u> :229-238.
Maggi et al. (2000), "Highly Swellable Multi-Layer Tablets to Prolong the Residence Time of the Delivery in the Stomach," <i>Journal of Controlled Release</i> <u>64</u> :269-347.
Oth et al. (1992), "The Bilayer Floating Capsule: A Stomach-Directed Drug Delivery System for Misoprostol," <i>Pharmaceutical Research</i> <u>9</u> (3):298-302.
Rao et al. (1988), "Swelling Controlled-Release Systems: Recent Developments and Applications," <i>International Journal of Pharmaceutics</i> <u>48</u> :1-13.
Reynolds et al. (1998), "Polymer Erosion and Drug Release Characterization of Hydroxypropyl Methylcellulose Matrices" <i>Journal of Pharmaceutical Sciences</i> <u>87</u> (9):1115-1123.
Shameem et al. (1995), "Oral Solid Controlled Release Dosage Forms: Role of GI-Mechanical Destructive Forces and Colonic Release in Drug Absorption Under Fasted and Fed Conditions in Humans," <i>Pharmaceutical Research</i> <u>12</u> (7):1049-1054.
Siepmann et al. (1999) "HPMC Matrices for Controlled Drug Delivery: A New Model Combining Diffusion, Swelling, and Dissolution Mechanisms and Predicting the Release Kinetics" <i>Pharmaceutical Research</i> <u>16</u> (11):1748-1756.
Yang et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric Configuration Drug Delivery System," <i>Journal of Pharmaceutical Sciences</i> <u>85</u> (2):170-173.

This Supplemental Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

As applicants have not yet received a first Action on the merits, no fee is required for filing this Supplemental Information Disclosure Statement. If, however, the PTO finds that for

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some reason a fee is found to be necessary, our Deposit Account No. 18-0580 may be charged therefor.

Respectfully submitted,

By:

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